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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/941,626	08/30/2001	Norman G. Anderson	42159	6779

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EXAMINER

MARSCHER, ARDIN H

ART UNIT PAPER NUMBER

1631

DATE MAILED: 09/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/941,626

Applicant(s)

ANDERSON ET AL.

Examiner

Ardin Marschel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-62 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-14, 16, and 59; drawn to a method for identifying a plurality of infectious particles in a sample via sequencing at least two nucleic acids, classified in class 435, subclass 6.
- II. Claims 15 and 17-19, drawn to a composition or true infectious particle-free germ stock, classified in class 435, subclass 243.
- III. Claim 20, drawn to an oligonucleotide, classified in class 536, subclass 23.1.
- IV. Claims 21-25, 27, 29-31, 33, 36, 38-41, 43, and 59; drawn to a method for producing antibody against an infectious particle via antibody binding to said infectious particle, classified in class 435, subclass 267.
- V. Claims 26, 28, 32, 34, 35, 37, 42, 44, 46, 50; drawn to a free or specific antibody directed to an infectious particle/antigen, classified in class 530, subclass 387.1.
- VI. Claim 45, drawn to making an antibody from a determination of an amino acid sequence of another antibody, obtaining DNA encoding a part of the determined amino acid sequence, expressing the DNA, and recovering the expressed antibody; classified in class 435, subclass 69.1.
- VII. Claims 47, 48, 55, and 59; drawn to a method of purifying an infectious particle antigen via antibody binding, classified in class 435, subclass 267.

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- VIII. Claims 49, 51, 53, and 56-59; drawn to an infectious particle antigen, classified in class 424, subclass 184.1.
- IX. Claim 52, drawn to a method for making an antigen via determining at least a part of the amino acid sequence of another antigen, obtaining DNA encoding a part of the determined amino acid sequence, expressing the DNA, and recovering the expressed antigen, classified in class 435, subclass 69.1.
- X. Claim 54, drawn to a vaccine comprising an infectious particle antigen, classified in class 424, subclass 184.1.
- XI. Claims 60-62, drawn to an apparatus for manipulating infectious agents, classified in class 422, subclass 188.

NOTES about apparent typographical errors in the instant claims:

Claims 50 and 56-58 cite a "method" in their respective first lines, however, they depend from a composition claim which contains a method therein as a product by process. Thus, claims 50 and 56-58 are assumed to be composition claims wherein the method of the claim from which they depend is being limited therein.

Claim 59 is a linking claim which depends from a number of method claims but also depends from claim 49 which is a composition claim, which cites a method therein. Thus, claim 59 is assumed to be directed to the method within claim 49 as a composition regarding the dependence from claim 49.

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Claims 61 and 62 are directed to an apparatus but cite dependence from vaccine claim 54. It is assumed that this claim 54 dependence is a typographical error and that dependence from claim 60 was intended.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups (I, II, VIII, X); Groups (III, VI, IX); Groups (IV, V, VII); and Group (XI) are independent or distinct inventions because they are directed to different chemical or apparatus types regarding the critical limitations therein. For Groups I, II, VIII, and X the critical feature is an infectious particle or antigen); for Groups III, VI, and IX the critical feature is nucleic acids or their use; and for Groups IV, V, and VII; the critical feature is an antibody; and for Group XI, the critical feature is a apparatus for infectious agent containment during nucleic acid extraction. It is acknowledged that various processing steps may cause an antigen to be directed as to its synthesis by a nucleic acid or an antibody made by nucleic acid expression, however, the completely separate chemical types of the inventions of the infectious particles/antigens, nucleic acids, antibody, and containment apparatus Groups supports the undue search burden if any two were searched together. Additionally, infectious particles/antigens, nucleic acids, antibodies, and containment apparati have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if examined together as compared to being searched separately. Also, it is pointed out that processing that may connect two Groups does not prevent them from being viewed as distinct because enough processing can result in producing any composition from any other composition

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if the processing is not limited as to additions, subtractions, enzyme action, etc. Thus, the three Groupings of (I, II, VIII, and X); (III, VI, and IX); (IV, V, and VII); and (XI) are independent and/or distinct invention types for restriction purposes.

The inventions of Group I and Groups II, VIII, and X are related as process of making and products made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the identification of infectious particles, vaccines therefrom, and infectious particle antigens may be alternatively made or identified by screening assays directed to either infectious process assays or immune reaction assays that do not involved sequencing as in Group I. Additionally, the compositions of Groups II, VIII, and X are directed to distinct materials in that infectious particles of Group I generally are complete or at least functionally infectious and identified or found from infectious or disease diagnosis whereas an infectious particle antigen as in Group VIII is a portion of such a particle which must be separately identified including utilizing subdivision of an infectious particle followed by screening assays for what specific antigen(s) are recognizable, but, for example, antibody assays. Additionally, the preparation and or determination of a vaccine made up of infectious particle antigens is a very specific material where some type of immune memory must be determined for anything that reasonably is a vaccine. Thus, the subject matter of Groups II, VIII, and X are directed to different and distinct

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materials both in terms of their making or identification as well as use thus documenting the undue search burden if they are searched together.

The inventions of Group III and Groups VI and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the oligonucleotides of Group III may be firstly utilized in the distinct methods of Groups VI or IX as well as alternatively for detection practice such as in hybridization assays or amplification via PCR. Additionally, the inventions of Groups VI and IX are distinct because Group VI is directed to an antibody from DNA encoding an amino acid sequence whereas Group IX is directed to using DNA for making an antigen of an infectious particle. An antibody and antigen of an infectious particle are different materials with different or distinct amino acid sequences, binding reactions, disease function etc. thus documenting the distinct subject matter which results in an undue search burden if they are searched together.

The inventions of Group IV and Group V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the antibody of

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Group V may be made by the alternative process of utilizing immune system cells to produce an antibody such as utilized for monoclonal or polyclonal antibody production.

The inventions of Group V and Group VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Group V may be alternatively utilized in a method of immunoassay for an infectious particle in disease diagnosis, such as an ELISA type assay.

The inventions of Groups IV and VII are distinct because they are directed to distinct methods of making an antibody (Group IV) and using an antibody for infectious particle antigen purification (Group VII). The making Group IV utilizes an infectious particle to find and produce an antibody wherein the exact opposite occurs in Group VII where an antibody is utilized for purifying an infectious particle antigen. The starting materials and ending materials are different. Thus the subject matter of these Groups is distinct from each other and would require a separate search if searched together thus documenting the undue search burden if they are searched together.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

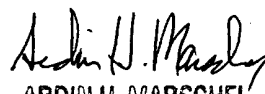
Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

September 10, 2003


ARDIN H. MARSCHEL
PATENT EXAMINER